

REMARKS

Claims 37-68 are pending in the present application.

The Examiner has required election in the present application between:

Group I, claims 37-48, drawn to a pharmaceutical composition of saquinavir and fatty acids, alcohols and antioxidants;

Group II, claims 49-67, drawn to a method of making a pharmaceutical composition of saquinavir and fatty acids, alcohols and antioxidants; and

Group III, claims 68, drawn to method of using a pharmaceutical composition of saquinavir and fatty acids, alcohols and antioxidants to treat patients.

**For the purpose of examination of the present application, Applicants elect, with traverse, Group I, Claims 37-48.**

Traverse is as follows.

Applicants note that the Examiner's arguments relating to lack of unity of invention urge that Mitsuyasu et al. report on a clinical trial comparing a hard gel capsule formulation of saquinavir to a soft gel capsule formulation of saquinavir, and therefore "the technical feature of the groups, which is the peptide, is not a contribution over the prior art." Applicants note that saquinavir, while it contains a some "peptide"-like amide bonds, is not a "peptide" in the traditional sense of being a polymer of amino acids. It is true that saquinavir itself is a known compound and so per se does not represent a contribution over the prior art.

However, the claimed invention is not directed to saquinavir *per se*, but rather to a composition of the drug and to methods for preparing and using the inventive formulation. Mitsavasu is completely silent regarding formulation of the saquinavir and so does not serve to destroy novelty or inventiveness of the presently claimed composition, which comprises

specific recited elements in recited proportions, none of which are disclosed or suggested by Mitsayasu. Accordingly, the present claims 37-68 describe a unified invention within Rule 13.1 of the PCT and so the instant restriction requirement should be withdrawn.

Furthermore, the present Groups I - III are related as a composition (Group I) and methods of making (Group II) or using (Group III) the composition. In the event that allowable subject matter is found in the claims of the presently elected Group I, Applicants insist that the Examiner rejoin claims of Groups II and III such as are commensurate in scope with the allowable composition claims into this application for examination. MPEP § 821.04.

#### Election of Species

The Examiner has also required an election of species of the fatty acid to be added to the composition and of the alcohol to be added to the composition. Applicants understand this election to be only for purposes of beginning examination and that, should the elected species be found allowable, the Examiner will go on to examine other species in the claims to determine patentability of the generic claims.

With such understanding, Applicants elect "oleic acid" as the species of fatty acid and "ethanol" as the species of alcohol.

Claims 37, 38, 40-53 and 55-68 are generic with respect to the fatty acid component of the composition. Claims 39 and 54 recite the elected species specifically.

Claims 37-39, 41-51 and 53-68 are generic with respect to the alcohol component of the composition. Claims 40 and 52 recite the elected species.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Registration No 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

- ☐ Attached is a Petition for Extension of Time.
- ☐ Attached hereto is the fee transmittal listing the required fees.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By   
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